OCT 31 2000

K002556

Pharmacia & Upjohn

510(k) SUMMARY – SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness is being submitted in accordance with 21 CFR 807.92(c).

1. Submitter's name, address, telephone number, contact person and date the summary was prepared:

Submitter:
Pharmacia & Upjohn Company
7000 Portage Road
Kalamazoo, MI 49001-0199
USA
Telephone: 616-833-4000

Contact Person:
Toni D. Elliott
Senior Manager, Regulatory Affairs
Pharmacia & Upjohn Company
592 Ceresia Court
Pickerington, OH 43147
USA
Telephone: 614-834-8629
Fax: 614-834-8631

Date Summary Prepared: July 21, 2000

2. Name of device, including trade name and classification name:

Trade/Proprietary Name: CeeOn™ EASYSERT Intraocular Lens Injector

Common Name: Intraocular Lens Injector

Classification Name: Intraocular Lens Guide (21 CFR 886.4300)

3. Identification of the legally marketed device to which substantial equivalence is being claimed:

Company:
Originally Submitted By:
Chiron Vision Corporation
555 West Arrow Highway
Claremont, CA 91711
Currently Marketed By:

	Bausch & Lomb Surgical, Inc. Telephone: 800-843-1137
Device:	Mport Multipiece Foldable Lens Placement System Model MP-30
510(k):	K970727
Date Cleared:	December 17, 1997

4. Description of the device that is the subject of the 510(k), including an explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):

The Ceeon EASYSERT Intraocular Lens Injector is a device used to assist in implanting Pharmacia & Upjohn's CeeOn Edge Model 911A foldable intraocular lens. It is designed to mechanically fold the lens and insert it into the eye during normal, small-incision cataract surgery. The intraocular lens is loaded into the cartridge, the tip cover is closed, and by screwing the barrel, the intraocular lens is moved into the tubular tip. The folded lens can then be delivered into the eye by pushing the piston. The EASYSERT is a plastic, single-use, disposable device.

The tip cover and cartridge body are made of high density polyethylene; the internal plunger and barrel are made of polypropylene (same as the tube, slide pusher and jackets of the predicate device); and, the internal piston is made of polycarbonate. The barrel of the injector is red, the internal piston and the cartridge body are gray. The internal plunger and the tip cover have no pigments added. The tip cover is coated with a medical grade fluid.

5. Statement of intended use:

The Pharmacia & Upjohn CeeOn EASYSERT Intraocular Lens Injector is a device used to assist in implanting Pharmacia & Upjohn's CeeOn Edge Model 911A foldable intraocular lens during normal, small-incision cataract surgery.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

Comparative Characteristics

Characteristics	Bausch & Lomb Mport (Predicate)	Pharmacia & Upjohn EASYSERT
Intended Use	Folds and delivers a multi-piece silicone intraocular lens into the eye during normal small-incision cataract surgery	Same
Operating Principle	• Intraocular lens is loaded into the inserter, which mechanically folds the lens and delivers it into the eye • Intraocular lens is delivered by direct forward motion applied to a syringe-type plunger	• Same • Same (Intraocular lens is folded by rotating a screw device creating forward motion; the lens is finally delivered into the eye by direct forward motion applied to a syringe-type plunger)
Folding Operation	Intraocular lens is loaded flat in an unstressed state and laterally compressed by the closure of a slider	Intraocular lens is loaded flat in an unstressed state and by the mechanical action of the internal plunger, the lens is folded by being moved into the tubular tip
Sterilization Method	Ethylene oxide	Gamma irradiation
Materials	• Polypropylene tube, slide pusher and jackets • Silicone O-ring	• Polyethylene tip cover, cartridge body • Polypropylene internal plunger, barrel • Polycarbonate internal piston
Surface Treatment	None	The tip cover is coated using Hydro-Sil-D.5, 360 Medical Fluid
Single-use	Yes	Yes
Patient Contact Portion of the Device	Cartridge tip and hand-piece tip	Tip cover and end of the internal plunger

7. Brief summary of non-clinical tests and results:

A qualified independent testing laboratory conducted the following tests on the EASYSERT Intraocular Lens Injector / components.

High density polyethylene tip cover coated with Hydro-Sil-D.5
Cytotoxicity (ISO elution method)
Sensitization test on guinea pigs – extract (ISO maximization method)

0217

Intraocular irritation (anterior chamber) study in rabbits (ISO 10993)
Physicochemical tests of plastics (USP)

Gray pigmented high density polyethylene (cartridge body)
Cytotoxicity (ISO elution method)
Intraocular irritation (anterior chamber) screening study in rabbits (ISO 10993)
Physicochemical tests of plastics (USP)

The test results indicate the materials are non-toxic, non-irritating and non-sensitizing.

The performance testing conducted on the CeeOn EASYSERT Intraocular Lens Injector evaluated the following characteristics of lenses after being subjected to delivery through the injector.

Back focal length
Resolution
Overall diameter
Loop angle
Optic decentration
Amount of touch
Compression force and decay
Axial displacement
Fold lines on the lens surface
Optic damage / loop damage
Loop pull strength

The test results indicate the CeeOn EASYSERT Intraocular Lens Injector reliably delivers CeeOn Edge Lens Model 911A without significantly impacting the optical performance, the dimensions or the cosmetic appearance of the lens.

8. Conclusion

Based on the results of the performance and biocompatibility testing, Pharmacia & Upjohn concludes that the CeeOn EASYSERT Intraocular Lens Injector is a safe and effective device for delivering the CeeOn Edge Lens, Model 911A.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2000

Toni D. Elliott
Senior Manager, Regulatory Affairs
Pharmacia & Upjohn Company
592 Ceresia Court
Pickerington, OH 43147

Re: K002556
Trade Name: CeeOn™ EASYSERT Intraocular Lens Injector, Model IMP-1
Regulatory Class: I, Reserved
Product Code: 86 MSS
Dated: August 16, 2000
Received: August 17, 2000
Amended: August 25, 2000

Dear Ms. Elliott:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may not market this device, however, until such time as the premarket approval application (PMA) for the CeeOn™ Edge Model 911A Intraocular Lens is approved. When the device is marketed, it will be subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification subject to the approval of the CeeOn™ Edge Model 911A Intraocular Lens PMA. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

David M. Whipple

for A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications Statement

510(k) Number (if known) K002556

Device Name: CeeOn EASYSERT Intraocular Lens Injector

Indications for Use:

The CeeOn EASYSERT is used to assist in implanting CeeOn EDGE foldable lens Model 911A, 12.0D up to and including 28.0D, into the capsular bag during small-incision cataract surgery.

Additional Claims:

None

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Optional Format 1-2-96)

Joel C. Gloveri

(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K002556